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ProSpecT Giardia Controls

REF R24280

EN

1. INTENDED USE

ProSpecT™ Giardia Controls are quality control materials intended for use with ProSpecT Giardia Assays.

2. SUMMARY

ProSpecT Giardia Assays are solid phase immunoassays, which detect *Giardia* Specific Antigen (GSA 65). GSA 65 is produced as *Giardia* protozoa multiply within the host intestinal tract. The ProSpecT Giardia Controls demonstrate that the ProSpecT Giardia Assay is positive in the presence of GSA 65 (Positive Control) and negative in the absence of GSA 65 (Negative Control).

3. PRINCIPLE OF THE TEST

Antibody to GSA 65 is used to “capture” the antigen when it is present in aqueous extracts of human faecal specimens. A second antibody labelled with horseradish peroxidase enzyme (the conjugate) is added and binds to the captured GSA 65. The substrate for the enzyme, 3,3',5,5'-tetramethylbenzidine (TMB), is added and a coloured reaction product is formed. Colour development can be detected visually or spectrophotometrically. In a positive reaction, GSA 65 is present and a coloured reaction occurs. In a negative reaction, there is no GSA 65 or an insufficient level of GSA present and no coloured reaction product develops.

4. SYMBOL DEFINITIONS

REF

Catalogue Number

IVD

In Vitro Diagnostic Medical Device

Σ

Contains sufficient for <n> tests

i

Consult Instructions for Use (IFU)

$\leq 25^{\circ}\text{C}$

Temperature Limitation (Storage Temp.)

LOT

Batch Code (Lot Number)

Use By (Expiration Date)

Manufacturer

5. KIT CONTENTS, PREPARATION FOR USE AND STORAGE

See also **Precautions**, section 6.

The expiration date of each kit is stated on the package label.

Store all components at 2 to 8°C.

Before use, bring all reagents to room temperature (20 - 25°C) and mix gently. Return the unused reagents to the refrigerator after use.

The Controls are ready to use and may be dispensed directly from the dropper bottles in which they are supplied.



Instructions for Use

CONTROL+

Positive Control

Two dropper bottles containing 4 ml of a buffered solution with inactivated *Giardia* antigen, and antimicrobial agents.

CONTROL-

Negative Control

Two dropper bottles containing 4 ml of a buffered solution with a red dye, and antimicrobial agents.

6. PRECAUTIONS

IVD

The reagents are for *in vitro* diagnostic use only.

For professional use only.

Please refer to the Safety Data Sheet (SDS) and product labelling for information on potentially hazardous components.

HEALTH AND SAFETY INFORMATION

- Reagents are prepared from biological materials and should be handled as potentially infectious material. Discard using appropriate biohazard procedures.
- Do not pipette by mouth. Wear disposable gloves and eye protection while handling specimens and performing the assay. Wash hands thoroughly when finished.
- Specimens may contain potentially infectious agents and should be handled at Biosafety Level 2 as recommended in the CDC/NIH manual, “Biosafety in Microbiological and Biomedical Laboratories”, 5th Edition.

ANALYTICAL PRECAUTIONS

- Reagents are provided at the necessary working strength. Do not dilute.
- Do not use reagents beyond the expiration dates. Expiration dates are printed on each reagent label. Use of reagents beyond the expiration date may affect the accuracy of results.
- Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes when removing aliquots from reagent bottles.
- It is important to hold the dropper bottles vertically and that the drop forms at the tip of the nozzle. If the nozzle becomes wet, a drop of incorrect volume will form around the end and not at the tip; if this occurs dry the nozzle before progressing.

7. TEST PROCEDURE

REQUIRED MATERIALS PROVIDED

See **Kit Contents**, section 5

PROCEDURE

- 7.1. Bring controls to room temperature (20 to 25°C) before use.
- 7.2. Use the controls in the appropriate ProSpecT Giardia Assay following the test instructions contained in the Instructions for Use (IFU).

8. QUALITY CONTROL

The Positive and Negative Control serve as both reagent and procedural controls. The controls are intended to monitor for substantial reagent failure. The Positive Control will not ensure precision at the analytical assay cut-off.

9. RESULTS

Refer to the Procedure Card enclosed with the appropriate assay for colour interpretations.

10. PERFORMANCE LIMITATIONS

The validity of results with the ProSpecT Giardia Microplate Assay depends on the control reactions performing as expected. See the appropriate ProSpecT Giardia Assay **Quality Control** section.

ProSpecT Giardia Controls are intended for use only with ProSpecT Giardia Assays.

11. EXPECTED VALUES

Refer to the appropriate ProSpecT Giardia Assay IFU for the expected values of the ProSpecT Giardia Controls.

REPRODUCIBILITY

To measure reproducibility, three different lots of ProSpecT Giardia Positive and Negative Controls were randomly selected and tested with each of the ProSpecT Giardia Assays. Inter-assay or run-to-run variation was evaluated by testing each lot 5 times on each of 5 days. Intra-assay or within-run variation was measured by multiple testing of each lot within each assay. The following results were obtained with all assays. All Positive Controls were positive with at least 2+ intensity colour visually or OD > 0.30 (blanked value). All Negative Controls were negative with no colour visually or OD < 0.10.

ProSpecT is a registered trademark



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For technical assistance please contact your local distributor.

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